A SYSTEM AND METHOD FOR PULVERIZING STONES AND SCAR REMOVAL IN SOFT TISSUES

FIELD OF THE INVENTION

The present invention relates to a method for pulverizing physiological stones and removing scar tissues.

BACKGROUND OF THE INVENTION

During the past few years, a great number of laser systems have been used clinically for various surgical applications. There has been increased interest in pulsed holmium lasers at 2-μm and pulsed erbium lasers operating in the 3-μm region for tissue ablation as their radiation is absorbed by tissue water.

The range of clinical applications for these lasers is continually expanding due to the controllable qualities of cutting, welding, and coagulating tissue and the possibility of transmitted properties, which make these wavelengths attractive for minimally invasive surgical treatments. However as most clinical treatments in orthopedics, angioplasty, ophthalmology, or lithotripsy, are performed in a liquid environment, often in a non-contact mode, most of the laser energy is absorbed in the water and little is left for tissue ablation.

It has been shown that the leading part of the infrared radiation (IR) laser pulse creates a water-vapor channel bridging the water-filled space between the fiber tip and the tissue surface. Because steam has a low absorption in the IR (in contrast to water), the channel acts as a transmissive cavity for the remaining part of the laser pulse, which makes non-contact tissue ablation possible. The rapidly expanding, and subsequently collapsing, water-vapor channel, may cause mechanical tissue damage, the extent of which exceeds the penetration of the laser light in tissue.

Medical treatment of hard tissues entrapped in a cavity comprising physiological fluids is often difficult and involves considerable undesired side effects. Such a treatment typically includes various surgical procedures, such as stone pulverizing, removal of ligaments and scar tissues from the temporomandibular joint (TMJ) etc.

TMJ syndrome, and related joint diseases, are manifested by the formation of relatively hard tissues entrapped in the synovial fluid adjacent to said joint. One mode of treatment is by the removal of the scar tissue located inside the TMJ. The scar tissue may be formed by acute trauma (e.g. a car accident) or chronic trauma (e.g. clenching or grinding), due to synovitis, or due to lack of mobility. Such a hard tissue in the temporomandibular joint usually results in a limitation of jaw opening. Treatment requires *"passive motion"* physical therapy, and surgery.

A recent advance in oral and maxillofacial surgery includes the delivery of laser energy through an arthroscope to the joint area in order to remove the hard tissue, which procedure replaces open joint surgery. Typical treatment includes administration of Holmium laser to the joint area. The procedure is carried out at an ambulatory care center, with discharge within several hours of the procedure. Most patients are back to work within 4-5 days. The conservative nature of laser debridement of adhesions is a significant aid in the treatment of the problems associated with TMJ dysfunction.

U.S. Patent No. 5,582,190 to Slavin *et al.* teaches a Holmium-laser-based arthroscopic method for relieving symptoms caused by temporomandibular joint disorder in a patient. Their method is based on the following fourteen steps: (a) injecting a solution of lidocaine and epinephrine into a superior joint space of a temporomandibular joint of a patient, thereby providing distention thereof; (b) making a first vertical incision anterior to the posterior aspect of the tragus of the ear of the patient; (c) making a second vertical incision anterior to the first incision and below a line from the posterior aspect of the tragus of the ear to the lateral

canthus of the orbit; (d) perforating the superior joint space bluntly with a first cannula and a first blunt trocar inserted into the first vertical incision and a second cannula and a second blunt trocar inserted into the second vertical incision; (e) advancing the first and the second cannula; (f) removing the first and the second trocar; (g) placing an arthroscope through the first vertical incision, allowing direct visualization of the joint; (h) placing a switching stick through the second vertical incision; removing the second cannula; (i) providing a dual-channel cannula having a distal end, a proximal end, a first and a second channel, each extending from the proximal to the distal end; (j) inserting the dual-channel cannula over the switching stick into an anterior recess of the superior compartment of the joint; (k) removing the switching stick; (l) locking the arthroscope into the first channel of the dual-channel cannula; (m) inserting an optical fiber into the second channel of the dual-channel cannula, the optical fiber for channeling radiation from a holmium laser; and (n) performing a desired surgical procedure within the joint space. According to Slavin's invention, the first and a second 2.0 mm cannula and a first and a second blunt trocar are used.

An additional example of removing hard tissues from relative soft organs is the pulverizing of physiological stones, and more particularly, the removal of calcium stones from the salivary ducts. The mechanism of salivary stone formation is unclear, but seems to be multi-factorial. About 1% of people suffer from salivary stones. Most stones form in the sub-mandibular gland (85%) and the remainder in the parotid (15%).

The elimination of stones from the body, such as kidney stones and gallstones has been known for decades. Lithotripsy is the pulverization and removal of urinary or other calculi using a lithotripter. A lithotripter is capable of fragmenting kidney stones with ultrasound waves. The majority of patients (85-90%) are rendered symptom free and in 30-50% of cases, the stones are completely cleared from the salivary glands. The remainder retain some stone debris.

Erbium is a metallic element of the rare-earth group. Erbium is always found in combination with yttrium, another rare earth, and the ore is mined in the form of yttrium-aluminum-garnet (YAG).

The erbium YAG laser emits a 2940 nm wavelength beam of light. Due to the extremely strong absorption of its 3μm-radiation in biological tissue, the erbium laser has become a very useful and precise tool in surgery. The resulting penetration depths are around 2-3 μm and thus offer a minimal invasive and precise ablation of tissue.

Holmium lasers have an advantage when transmission of the laser beam over longer distances is required, such as when transmiting the energy from the apparatus to the kidneys, while Erbium lasers are effective for shorter distances as their energy can not be transmitted through standard silica fibers.

Erbium laser frequencies are not well suited for the treatment of soft tissues, but are highly effective for the treatment of hard tissues, because of the ability to pulverize these hard tissues. Consequently, Erbium YAG lasers are used in dentistry as substitute for the painful, noisy drill, especially for clearing the areas of tooth decay. These frequencies have no substantial effect on surrounding soft tissues, and therefore do not damage the gums, tongue, cheeks, etc.

The use of Erbium lasers for laser lithotripsy of salivary stones is unknown in the art. The idea of using Erbium lasers for endoscopic lithotripsy was initiated in 2001, but not for the salivary glands. Erbium lasers have been researched for urology for the removal of kidney stones (Chang *et al., Journal of Urology*, **<u>168</u>**:436-441, (2002)), and are well known for drilling of teeth.

U.S. Patent No. 6,375,651 to Grasso III *et al.* discloses a medical device, which requires a suction conduit, and an energy-transmitting conduit wherein at least some of the transmitted energy is directed to the distal region of the suction conduit. The said device includes an optical apparatus for directing the energy. The device has applications in lithotripsy and tissue-removal in a patient. Ho:YAG laser was claimed to be useful for such a procedures. The inventors also suggested to

utilize lasers based on thulium (Th), Erbium:yttrium-aluminum-garnet (Er:YAG) (190 to 350 nm), HF, DF, CO, and CO_2 in the mid-infrared region, and excimer lasers in the ultraviolet region. However the technology disclosed in this publication is unsuitable for pulverizing stones in the salivary ducts because suction is not possible in physiological conduits as small as the salivary ducts, which have a maximal diameter of 3 mm.

It is well acknowledged that introduction of a suction in the manner defined in this patent will promptly and irreversibly collapse the fragile salivary duct and this is probably the reason why the treatment of such small-diameter ducts is not defined specifically as embodiments of this patent .

U.S. Patent. No. 6,395,000 to Mitchell *et al.* discloses a medical laser system for ablating biological material. The system also includes an Er:YAG laser useful for various ophthalmic procedures, including capsulotomies, sclerostomies, excision of pupillary membranes, cutting of vitreous bands and iris margin. The system is described by the inventors to be also useful for a variety of urinary organ procedures such as kidney wall modification, stone (calculi) fragmentation and removal in the kidney, gall bladder and ureter (lithotripsy), transurethral incision of the prostate, prostatectomy, ureter lesion removal, vasal tissue removal, nephrectomy, vasovasotomy and lymph node modification. Moreover, the system supposed also to be useful for opening strictures in the aorta, modifying vessels at an aneurysm, for clearing vessels (angioplasty) and for removing clots. However, the system as described in aforementioned Mitchell's patent was not found useful for pulverizing stones in the salivary gland ducts.

SUMMARY OF THE INVENTION

The present invention is based on the surprising finding that erbium yttrium-aluminum-garnet (Er:YAG) laser is useful for treating hard tissues entrapped in a cavity comprising body fluids, wherein said cavity diameter is less than 3 mm .

This is surprising in view of the fact that typically for such small cavities heating of the cavity and the fluid in it is a major problem that may cause substantial damage to the tissue.. This problem of heating is of no concern in the typical uses of Er:YAG in treating hard tissue present in large cavities such as kidneys (Chang *et al. Supra*) as in such large cavities the bulk of the tissue and liquid may absorb part of the heat. This finding is also contrary to the typical use of holmium lasers for removal of stones from small cavities and further more it was found by the inventors of the present invention that holmium laser does not give satisfactory results as the stone is disintegrated to fragments that are too large for convenient flushing..

Thus, the present invention concerns a method for the treatment of hard tissues present in a fluid-filled body cavity, the cavity having a diameter of 3 mm or less, the method comprising: applying to, said hard tissue or to the vicinity of said hard tissue a laser beam produced by Er:YAG laser device.

The term *"hard tissue'* in the context of the present invention refers for example to calculi (stones) present in air physiological conducts, or present in small cavities such as the salivary glands; as well as to hard fibrotic tissue, for example produced by scarring in the temporomandibular joint The term *"fluid-filled body cavity"* refers both to a fluid filled lumen of a physiologic conduit such as salivary glands, as well as to small fluid filled cavities such as those present in the temporomandibular joint. In accordance with the present invention, the fluid-filled body cavity has a diameter of 3 mm or less, this being contrary to the publication of Chang *et al (supra).* wherein the fluid-filled cavity is kidney having a substantially larger diameter.

The term "*in the vicinity*"- means from contact and up to 1-2 mm away from the stone, at which distance the energy can still reach the stone due to the "bubble" effect .

The method of the invention is achieved by applying either directly to the hard tissue, or to the fluid present in the vicinity of said hard tissue, preferably at a

distance of up to 1-2 mm the laser beam so that its focus is either at or at said vicinity to the treated hard tissue. Typically, in accordance with the present invention, the parameters of the laser beam of between 200-1000 millijoules/mm^2, preferably 300-700 millijoules/mm^2, most preferably 300-500 millijoules/mm^2

The beam is produced by an Er:YAG laser device, contrary to state of the art methods wherein the hard tissue in the small cavities is treated by other lasers such as Holmium laser. As will be shown in the example, the use of Er:YAG laser has the beneficial effect that the fragments of the calculi produced, have a very small diameter, and thus can be easily flushed out from the cavity.

Preferably, in accordance with the present invention, the laser device is located inside an endoscope.

By another aspect, the present invention concerns a system for treatment of hard tissue present in a fluid-filled body cavity, the cavity having a diameter of 3 mm or less, the system comprising an endoscope for visualizing the interior of the treated cavity, and a device for the production of an Er:YAG laser beam. Preferably, the device is in fact a hollow endoscope through which the laser beam is administered.

The laser beam preferably is adapted to generate the beam having the parameters of 200-1000 millijoules/mm^2.

Typical treatment time can be determined empirically on a case by case basis as the disintegration of the hard tissue is typically continuously monitored by an endoscope. Typical treatment times are about 1 to 5 minutes.

In accordance with the invention the fluid-filled body cavities are ducts of the salivary glands and preferably the hard tissue is calculi, preferably a salivary stone.

According to one particular embodiment the endoscope is a Nahlieli type sialoendoscope, and the delivery of said laser beam is provided by a curved optical fiber.

The method of the present invention may be used for the disintegration and subsequent removal of calculi and in particular for disintegration and removal of salivary stones.

By another option the present invention may be used for relieving symptoms caused by scars and other temporomandibular joint disorders in a patient, particularly wherein the fluid-filled joint (being the fluid-filled cavity) has a diameter of less than 3 mm. As in the case of calculi, also for the treatment of scar tissue, the laser beam is directed to said scars at close proximity so as to disintegrate the hard tissue. Said Er:YAG laser is effective in the pulverization of said scars, to fragments having a diameter of less than 2 mm. Specifically, the scars are selected from hard tissues caused due to diseases or disorders of the TMJ and its surrounding regions.

The method of the invention is typically carried out by the following steps: (a) providing an endoscope for visualizing the interior of the body-filled cavity such as salivary glands; (b) providing an Er:YAG laser device to generate a laser beam in order to pulverize the hard tissue such as the salivary stones; (c) applying a laser beam produced by the device through said endoscope to the hard tissue to be treated or to its vicinity . The laser beam is directed at said hard tissue (such as the salivary stones) or at close enough proximity to the stones so that said Er:YAG is capable of pulverization of said stones in the way calculi fragments having a diameter less than 2 mm are produced.

More specifically, the endoscope is a Nahlieli type sialoendoscope. Preferably the delivery system of said laser beam is by a curved optical fiber. Typically the laser beam is transferred from the Er:YAG device (which may be for example a standard device used in dentistry), by a fiber for transmittal of laser beams which may be germanium oxide glass, sapphire or a hollow waveguide. .

Typically the length of the fiber incorporated in the endoscope is 10-20 cm.

BRIEF DESCRIPTION OF THE DRAWINGS

In order to understand the invention and to see how it may be carried out in practice, some preferred embodiments will now be described, by way of non-limiting examples only, with reference to the accompanying drawings, in which:

Fig. 1 is a schematic illustration of the temporomandibular joint and a magnified view thereof ;

Fig. 2 is a schematic illustration of the salivary glands and ducts where salivary stones may develop.

Fig. 3A shows a manner of treatment of salivary stones;

Fig. 3B shows the positioning of the laser-emitting fiber in a salivary duct for the treatment of stones;

Fig. 4A and **Fig 4B** is a schematic illustration of two types of Nahlieli sialoendoscopes; and

Fig. 5 is a schematic illustration of an add-on apparatus for attachment into a standard Er:YAG laser device.

DETAILED DESCRIPTION OF THE SPECIFICATION

As set forth above, it is the core of the present invention to treat hard tissues entrapped in a cavity comprising body fluids, wherein said cavity has a diameter of less than 3 mm so treatment of the hard tissue is achieved without causing a substantial heating of the fluid and the small sized fluid filled cavity . Such a heating presents a major problem and prior the present invention prevented effective and safe treatment of hard tissues in such small cavities.

Prior to the present invention there was no satisfactory solution for the treatment of hard tissue entrapped in small, fluid-filled cavities, and there was no way to provide a treatment that would enable on the one hand, to disintegrate the hard tissue to small enough fragments to be easily flushed out, and on the other hand, to do so without substantial (i.e. tissue damaging) temperature increase in the fluid-filled small cavity.

Two examples are hereto provided, wherein the first is the treating of scars and other diseases and disorders in the temporomandibular joint (TMJ). The second is treating of calcium stones, especially those located in the mandibular salivary ducts. Those two examples and the following description which is provided below, along all chapters of the present invention, are described to enable any person skilled in the art to make use of said invention and set forth the best modes contemplated by the inventor of carrying out this invention.

Various modifications, however, will remain apparent to those skilled in the art, since the generic principles of the present invention have been defined specifically to provide the erbium yttrium-aluminum-garnet (Er:YAG) laser system.

Reference is made now to **Fig. 1** describing the TMJ **1** located in the joint of the mandibular and maxillary bones. A magnified presentation of said TNJ is presented to comprise of a connective tissue **(2a)** and a disc **2(b)** .

Reference is made now to **Fig. 2**, schematically presenting the salivary glands: parotid duct **21** communicating the mouth with the accessory parotid gland **22** the parotid gland **23** and the submandibular gland **24** and the sublingual gland **25**.

For endoscopic laser lithotripsy of salivary stones, it is determined that 85% of salivary stones are located in the sub-mandibular gland **24** and 15 % in the parotid **22, 23** glands. This is the area of the mouth and jaws. Most stones are composed of calcium phosphate. Typical size range is 5-20 mm. Complete fragmentation requires fragments less than 2 mm, so that they can be effectively disintegrated.

Fig. 3A shows the laser applied to the salivary glands of a patient **130**, and delivered through the mouth cavity..

.**Fig. 3B** shows reference block diagram **135** of the placement of the endoscope and the optic fiber in salivary ducts , wherein **137** is the stone, 138 is the endoscope and 136 the laser fiber.

The endoscopes used such as in Figs 4A and 4B may be a Nahlieli type sialoendoscope, and delivery of said laser beam is by a curved optical fiber . The Nahlieli sialoendoscope, as such as the device Type 1 or 2 commercially available by Karl Storz Ltd. This is an endoscope useful for the diagnosis and treatment of inflammatory salivary gland diseases and for minimal temporo-mandibular-joint arthroscopy (denoted in the present invention in the term 'Nahlieli type sialoendoscope'). The hereto-defined Storz's Nahlieli sialoendoscope usually comprising two separate channels, with two blunt obturators and two LUER-lock adapters, curved channel for instruments up to 3 Fr., O.D. 1.3 mm, straight channel for use with the commercially available Miniature Telescope 28620 with lateral LUER-lock adapter for irrigation, O.D. 1.3 mm, working length 4 cm, overall length 10.7 cm.

Reference is made now to Fig. **4A**, presenting a side view of a Karl Storz commercially available Nahlieli sialoendoscope, comprising a handle and blunt obturator, for use with a miniature telescope diameter 2.3 mm x 1.3 mm, working length 12 cm, and an operating sheath with obturator valve. Similarly, Fig. **4B** is presenting a side view of another commercially available Nahlieli sialoendoscope comprising with two separate channels, with two blunt obturators and two LUER-lock adaptors, curved channel for instruments up to 3 Fr., O.D. 1.3 mm, straight channel for use with miniature telescope with lateral LUER-lock adaptor for irrigation, O.D. 1.3 mm, working length 4 cm, overall length 10.7 cm.

It is in the scope of the present invention, wherein the laser is an ErbiumYAG laser ,

Reference is now made to **Fig. 5** which shows an apparatus which is part of a system for carrying out the invention **500** . This apparatus is a focusing hand piece which attaches, at its proximal end **501** to a standard dental Erbium laser delivery fiber **502**, from which the original dental hand piece has been removed (not shown). The hand piece houses focusing lenses (e.g. ZnSe lenses) **503** to focus the beam emitted from the laser fiber into the endoscopic fiber **504**. The endoscopic

fiber **504** is attached at the distal end of the hand piece through a quick connect mechanism **505** such as an SMA connector. The endoscopic fiber **504** is inserted into the operating channel of the Nachlieli endoscope (for example as shown in Fig. 4A or 4B). A luer lock (not shown) may be incorporated over the SMA connector to firmly secure the fiber and the hand piece to the endoscope so that the surgeon may hold the entire device in one hand.

EXAMPLE 1: The use of an Erbium laser for lithotripsy of salivary stones

A. Set up:

Erbium laser used for the tests was a commercial OpusDuo dental laser produced by Lumenis Ltd., Israel. This laser is a free-running, 2.94 μm laser which emits 250 μsec pulses at a maximum rate of 20 Hz. Energy per pulse can be adjusted from 100 mJ to 1000 mJ. Maximum average power is 20 Watt.

The laser beam is delivered through a flexible, metal, hollow fiber to a handpiece which may be detached. Beam spot size at the handpiece output aperture is 1 mm.

Some of the tests were conducted using the standard system handpiece fitted with short sapphire tips (straight or tapered) to deliver the energy to the stones while some of the tests were conducted using various commercially available infrared fibers such as sapphire fibers (Photran Inc., U.S.A.), hollow glass fibers (Polymicro, U.S.A.) or germanium oxide glass fibers (Infrared Fiber Systems, U.S.A.).

1 mm. core fibers were "butt" coupled to the system handpiece while smaller diameter fibers were connected using ZnSe lenses to focus the laser beam into the fiber.

Fiber diameters were 1 mm. or 0.75 mm, core.

B. Test Results:

In vitro lithotripsy of human, extracted, salivary stones was conducted both in air and in water to test optimal fragmentation parameters. In air, 200 mj with a spot of 1 mm and a frequency of 20 Hz resulted in efficient fragmentation to dust-like particles. Energy increase to 300 mj appeared clinically to be too aggressive with substantially larger fragments. In all cases fragmentation was conducted in contact or close contact to the stone. While fragmentation was found to be clinically efficient, lithotripsy in an air environment resulted in rapid contamination of the fiber output surface by stone debris which caused fiber damage. Even small salivary stones could not be fragmented before onset of this catastrophic damage mechanism. Contamination persisted even with a fiber-stone distance of 3-4 mms. though efficiency decrease due to beam divergence out of the fiber. Additionally large fiber-stone distances are endoscopically not practical.

To overcome this problem, fragmentation was conducted in a water filled container with the fiber tip in contact with the stone. It was found that in a water environment fiber tip durability is increased even though laser energies have to be increased to obtain clinically efficient fragmentation rates. Using a 1 mm spot size, threshold for clinically efficient fragmentation was found to be 300 mJ per pulse, while optimal range was 500-700 mJ per pulse. Optimal pulse rates were 15-20 Hz. Stone fragmented to microscopic, dust-like particles which floated in the water, with occasional larger fragments (2-3mm) which broke off particularly from softer stones.

The surface of a 1 mm. sapphire tip, in contact with the stone under water, did not exhibit any damage or degradation at all energy levels up to 1000 mJ, the maximum energy available from the laser.

Use of the smaller fiber diameter resulted in more efficient fragmentation due to the higher energy densities, but resulted in fiber tip damage with some of the fibers used.

EXAMPLE 2: Comparative results – Er:YAG laser to Holmium laser

The comparison was perform between Er:YAG laser and Holmium laser the latter being the standard laser used for lithotripsy in urology.

Comparison was carried out *in vitro*, testing the size and nature of fragmentation of extracted, human salivary stones placed in a water filled metal container which was to simulate a small cavity filled with liquid. Delivery of the Holmium laser was through standard, commercial low-OH silica fibers.

Test confirmed literature report that fragmentation efficiency of Erbium is roughly twice that of Holmium.

Fragmentation rate of Erbium at 10 Hz, 0.5 J/pulse was similar to that of Holmium at 10 Hz, 1J. These are the standard Holmium parameters used in clinical work. Additionally test showed that stone fragments following Erbium lithotripsy are smaller than with Holmium.

This was visually observed by the fact that for the same stones, most Holmium fragments immediately sunk and accumulated at the bottom of the container while with the Erbium, fragments floated in the water as a *"cloudy"* suspension.

These results indicate that the method of the invention is more effective in disintegrating stones, in particular salivary stones, than standard treatment with Holmium laser.

Having described the invention with regard to certain specific embodiments thereof, it is to be understood that the description is not meant as a limitation, since further modifications will now suggest themselves to those skilled in the art, and it is intended to cover such modifications as fall within the scope of the appended claims.